



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,158	12/11/2006	Mark E. Samuels	760050-154	4554
27162 7590 12/14/2009 CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI, STEWART & OLSTEIN 5 BECKER FARM ROAD ROSELAND, NJ 07068				
EXAMINER MONSHIPOURI, MARYAM				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
12/14/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/552,158

**Applicant(s)**

SAMUELS ET AL.

**Examiner**

Maryam Monshipouri

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-127 is/are pending in the application.
- 4a) Of the above claim(s) 1-32, 44-91 and 98-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 33-43, 92-97 and 118-127 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: \_\_\_\_\_

Applicant's response to restriction letter of 8/20/2009 is acknowledged. Applicant elected Group II, claims 33-43 and 91-97, and newly added claims 118-127, SEQ ID NO:12 and the disorder anemia of inflammation and antisense species without traverse. Claims 1-32 and 44-90, 98-117 and SEQ ID NO:10-11 and all other species recited in the previous office action except for antisense are hereby withdrawn as drawn to non-elected invention.

In view of applicant's request the disease of anemia and inflammatory anemia which now appear in a single claim (namely claim 42) will be examined together.

Regarding restriction among SEQ ID NO:10-12 applicant argues that all three sequences are transcripts of the same gene and a search of SEQ ID NO:12 (the elected invention) should show proteins with similarity to SEQ ID NO:10 and 11 as well and therefore all said sequences should be examined together.

This argument was fully considered but was found **unpersuasive**. The fact that SEQ ID NO:10-12 have some structural similarity relative to one another does not necessarily justify rejoinder. Applicant is well aware that splice variant of a single gene are patentable over one another. However, if applicant admits under record that SEQ ID NO:10-12 are not patentable over one another the examiner will rejoin said sequences in response to applicant's admittance.

It is noted that claim 91 which is directed to a method of identifying compositions comprising modulators, currently incorporated into Group II due to inadvertent error should be rejoined with Group I. Therefore the examiner hereby rejoins said claim with

Groups I which is currently withdrawn. The examiner regrets any confusion that said error might have caused applicant.

Upon further review of the previous office action it was deemed necessary to further restrict the elected invention as following:

**Group IIA:** claims 33-43 and 123-127, drawn to a method of treating a disorder utilizing HFE2A modulators.

**Group IIB:** claims 92-97 and 118-122, drawn to a method of treating a disease of iron metabolism utilizing gene products of HFE2A gene.

The inventions listed as Groups IIA-B above do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding technical features as following: the special technical features of Groups IIA and IIB are: method of use of modulators and method of use of HFE2A gene products, respectively, which are method of use products which share no structural or functional similarity.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

\*\*\*

Application/Control Number: 10/552,158  
Art Unit: 1656

Page 5